II. BRIEF DESCRIPTION OF CERTAIN ILLUSTRATED EMBODIMENTS

The present inventions, as defined by the claims, are directed generally to catheter assemblies. As illustrated for example in Figure 42, a formal version of which is reproduced below for the Examiner's convenience, a catheter probe 404 in accordance with one embodiment of a present invention includes a catheter 12, a handle 18 with a ***strain relief element 21***, and a pull wire 60 with a ***proximal portion*** that extends along the ***exterior*** of the catheter 12. The pull wire 60 may be secured to the handle 18. In the exemplary embodiment illustrated in Figure 42, the pull wire 60 is secured to the handle's strain relief element 21 with an anchoring element 406.

FIG. 42

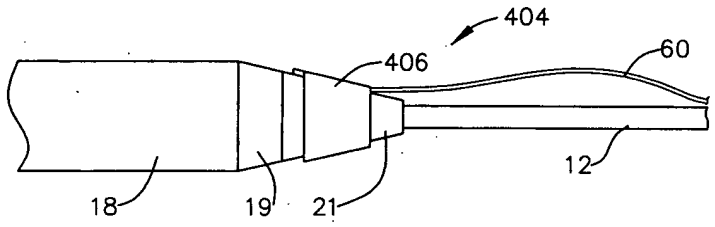
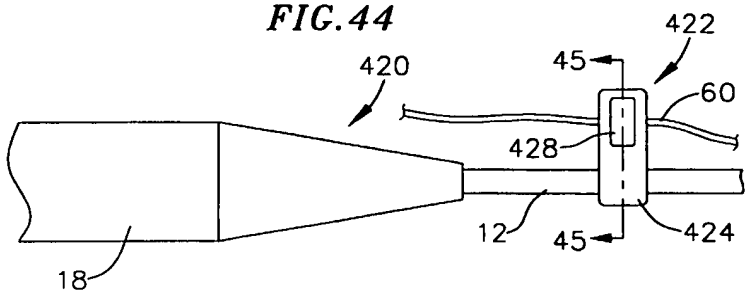


Figure 42 of the Present Application

Another exemplary embodiment of a present invention is generally represented by reference numeral 420 in Figure 44, a formal version of with is reproduced below for the Examiner's convenience. Here, a gripping mechanism 422 is provided ***in spaced relation to the handle 18***. The gripping mechanism 422 holds the proximal portion of the pull wire 60 relative to the catheter 12.

FIG. 44



Figur 44 of the Present Application

III. PRIOR ART REJECTIONS

A. The Rejections

Claims 10-12, 15-23 and 27-37 have been rejected under 35 U.S.C. § 102 as being anticipated by the Whayne patent (US 6,071,279). Claims 13 and 24-26 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Whayne patent (US 6,071,279) and the Brennen patent (US 5,439,006). The rejections under 35 U.S.C. §§ 102 and 103 are respectfully traversed. Reconsideration thereof is respectfully requested.

B. Claim Interpretation Issues Raised By the Office Action

In response to the arguments in the amendment dated March 21, 2002, the Office Action states that "[a]pplicant's arguments are narrower than the scope of the claims" and that "[t]he claims do not have enough structural language to overcome the art of record." [Office Action at page 3.] This somewhat cryptic statement provides little guidance as to exactly which of applicant's many arguments the Office Action is referring to. Nevertheless, given that the bulk of applicant's arguments concerned two aspects of the claimed combinations, i.e. the "***strain relief element***" recited in independent claim 10 and the "***exterior surface*** of the catheter body" recited in independent claims 10 and 22, it would appear that the Office Action has concluded that these terms must be augmented with additional "structural language" before the claimed combinations will be patentable over the prior art of record.[1] This conclusion is respectfully traversed.

As discussed in *In re Cortright*, 49 USPQ2d 1464, 1467 (Fed. Cir. 1999), claims in an application are to be given their broadest reasonable interpretation. This interpretation must be "consistent with the specification" and "consistent with the one that those skilled

[1] Applicant notes for the record that that the patentability of the claimed inventions is derived from the claimed combinations of elements as a whole, rather then from the presence of a particular element (or elements) in the claimed combinations.

in the art would reach." *Id.* One way to determine the interpretation which one of skill in the art would ascribe to a particular term is to review analogous prior art references. *Vitronics Corp. v. Conceptronic, Inc.*, 39 USPQ2d 1573, 1578-79 (Fed. Cir. 1996) ("prior art can often help to demonstrate how a disputed term is used by those skilled in the art"). As such, "the PTO's interpretation of claim terms should not be so broad that it conflicts with the meaning given to identical terms in other patents from analogous art." *In re Cortright*, 49 USPQ2d at 1467.

With respect to the use of the term "strain relief element" in the present application, the specification identifies one example of a strain relief element as being represented by reference numeral 21 in Figures 41 and 42. Figures 41 and 42 show the strain relief element 21 to be a structure that is associated with the handle 18 and the proximal end of the catheter 12. Strain relief elements were, at the time of the present invention, notoriously well known devices that reduce the mechanical strains on the proximal portion of a catheter as it is bent relative to a handle or other structure. For this reason, the present application did not go to great lengths to explain what a strain relief element is.[2] Nevertheless, in the event that the Examiner determines that there may be a question as to how one of ordinary skill in the art would interpret the term "strain relief element," attached hereto as Exhibits 1-5 are a number of analogous prior art references. The Examiner's attention is directed to the following aspects of the references:

1. U.S. Patent No. 4,583,968 (Exhibit 1) – see reference numeral 15' in Figure 1 and column 3, lines 31-35;
2. U.S. Patent No. 5,167,647 (Exhibit 2) – see reference numeral 5 in Figure 1 and column 2, lines 43-50;
3. U.S. Patent No. 5,499,981 (Exhibit 3) – see reference numeral 163 in Figure 55 and column 15, lines 29-31;
4. U.S. Patent No. 5,507,995 (Exhibit 4) – see reference numeral 86 in Figure 1 and column 6, lines 58-63; and
5. U.S. Patent No. 5,527,325 (Exhibit 5) – see reference numeral 52 in Figure 1 and column 12, lines 52-54.

[2] "[A] patent need not teach, and preferably omits, what is well known in the art." *Hybritech Incorporated v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986).

In view of the foregoing, applicant respectfully submits that one of ordinary skill in the art would interpret the "strain relief element" recited in claim 10 as a device that is associated with the claimed "handle" and is used to reduce mechanical strains on the proximal portion of the claimed "catheter body."

Turning to the term "***exterior surface*** of the catheter body," which is recited in independent claims 10 and 22, applicant respectfully submits that there is no reasonable interpretation of this term other than its ordinary English language meaning, i.e. the outside surface of the catheter body.

C. Discussion Concerning Claims 10-21

Independent claim 10 calls for a combination of elements comprising "a handle including a handle body and a ***strain relief element***," "an elongate catheter body" and "a control element defining a distal portion operably connected to the distal portion of the catheter body and a proximal portion extending along the ***exterior surface*** of the catheter body and ***secured to the strain relief element***."

1. The rejection under U.S.C. § 102

Applicant respectfully submits that the Whayne patent fails teach or suggest a number of elements in the combination defined by independent claim 10. For example, the Whayne patent fails to teach or suggest the use of a "strain relief element." The text of the Whayne patent does not even include the word "strain" or the word "relief." Nevertheless, the Office Action has apparently taken the position that element 68 in Figure 1 of the Whayne patent corresponds to the claimed "strain relief element." [Office Action at Page 2.] As clearly illustrated in Figure 1 (which is reproduced on the following page) and described in column 11, lines 45-57 of the Whayne patent, element 68 is a ***steering mechanism*** (i.e. a rotatable knob) that is used to pull steering wires in the Whayne catheter. Applicant respectfully submits one of ordinary skill in the catheter art

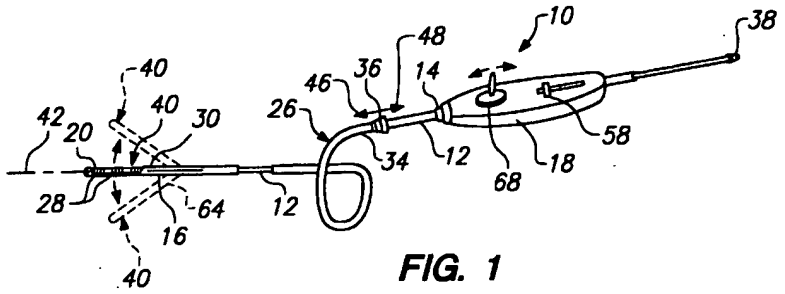


FIG. 1

Figure 1 of the Whayne Patent

who has reviewed the present application would understand that the Whayne steering mechanism 68 is not a "strain relief element" as is asserted in the Office Action. In addition to conflicting with the present application, the Office Action's interpretation of the term "strain relief element" impermissibly conflicts with the meaning given to this term in other patents from the catheter art. [See Exhibits 1-5.] There is simply no reasonable interpretation of the term "strain relief element" that would be broad enough to read in the Whayne steering mechanism 68.

The Whayne patent also fails to teach or suggest "a control element defining ... a ***proximal portion*** extending along the ***exterior*** surface of the catheter body and secured to the strain relief element." The Office Action appears to have taken the position that element 152 (illustrated in Figures 21-24 and described in column 16, lines 16-18 of the Whayne patent) corresponds to this aspect of the claimed combination. The Whayne patent specifically states that "the catheter tube 12 includes an ***interior lumen 156,*** which accommodates sliding passage of the pull wire 152." [Column 16, lines 14-16, emphasis added.] Applicant respectfully submits that one of ordinary skill in the would certainly understand that an "***interior*** lumen" does not correspond to an "***exterior*** surface" and, therefore, that the ***proximal portion*** of the Whayne pull wire 152 clearly does not extend along the ***exterior*** surface of the catheter tube 12.

As the Whayne patent fails to teach or suggest each and every element of the combination recited in independent claim 10, applicant respectfully submits that claims

10-12 and 15-21 are patentable thereover and that the rejection under 35 U.S.C. § 102 is improper and must be withdrawn.

2. The rejection under 35 U.S.C. § 103

With respect to the rejection of dependent claim 13, the Brennen patent discloses a steerable device including a tubular member 10, a pull wire 12 and a handle 28. Applicant respectfully submits that the Brennen patent fails to remedy the deficiencies in the Whayne patent described above with respect to independent claim 10. For example, the Brennen patent does not teach or suggest the use of a "strain relief element." The Office Action appears to have taken the position that element 34 in the Brennen patent corresponds to the claimed "strain relief element." [Office Action at page 2.] In contrast to the manner in which this term would be interpreted by one of ordinary skill in the art who has reviewed the present application, element 34 is actually a pivotable lever that is used to pull the pull wire 12 in response to sliding movement of slidable member 32. [Column 7, lines 16-49.] In addition, and as noted above, the Office Action's interpretation of the term "strain relief element" impermissibly conflicts with the meaning given to this term in other patents from the catheter art. [See Exhibits 1-5.]

The Brennen patent also fails to teach or suggest "a control element defining ... a ***proximal portion*** extending along the ***exterior*** surface of the catheter body and secured to the strain relief element." The proximal portion of the Brennen pull wire 12 is clearly located ***within the interior*** of the tubular member 10. Applicant respectfully submits that one of ordinary skill in the would certainly understand that the ***interior*** of the Brennen tubular member 10 does not correspond to an "***exterior*** surface" of a catheter.

As the Whayne and Brennen patents fail to teach or suggest the combination of elements recited in claim 13 (which by definition includes the combination of elements recited in independent claim 10), applicant respectfully submits that the rejection of claim 13 under 35 U.S.C. § 103 is improper and must be withdrawn.

C. Discussion Sp cifically Concerning Claims 22-37

Independent claim 22 calls for a combination of elements comprising "a handle," "an elongate catheter body," "a control element defining a distal portion operably connected to the distal portion of the catheter body and a proximal portion extending along the ***exterior*** surface of the catheter body" and "an apparatus, located in spaced relation to the handle body, adapted to secure the proximal portion of the control element in predetermined relation to the catheter body."

1. The rejection under U.S.C. § 102

Applicant respectfully submits that the Whayne patent fails teach or even remotely suggest a number of elements in the combination defined by independent claim 10. For example, and as described in detail in Section III-C-1 above, the Whayne patent fails to teach or suggest a combination of elements including "a control element defining ... a ***proximal portion*** extending along the ***exterior surface*** of the catheter body." The Whayne pull wire 152 instead passes through a ***interior lumen*** 156 within the catheter tube 12. One of ordinary skill in the would certainly understand that an "***interior*** lumen" does not correspond to an "***exterior*** surface" and, therefore, that the ***proximal portion*** of the Whayne pull wire 152 does not extend along the exterior surface of the catheter tube 12, as set forth in the combination defined by independent claim 22.

The Office Action also appears to have taken the position that element 36 in the Whayne patent corresponds to the claimed "apparatus ... adapted to secure the proximal portion of the control element in predetermined relation to the catheter body." [Office Action at page 2.] Element 36 is merely a gripping surface for the sheath 26 and is not used to secure anything to the catheter tube 12.

As the Whayne patent fails to teach or suggest each and every element of the combination recited in independent claim 22, applicant respectfully submits that claims 22, 23 and 27-37 are patentable thereover and that the rejection under 35 U.S.C. § 102 is improper and must be withdrawn.

2. The rejection under U.S.C. § 103

Turning to the rejection of claims 24-26 under 35 U.S.C. § 103, applicant respectfully submits that the Brennen patent fails to remedy the deficiencies in the Whayne patent described above with respect to independent claim 22. For example, the Brennen patent does not teach or suggest the use of a control element with a proximal portion extending along the ***exterior*** surface of the catheter body. The proximal portion of the Brennen pull wire 12 is, instead, located ***within*** the tubular member 10. The Brennen patent also fails to teach or suggest an apparatus, located in spaced relation to the handle 28, that secures the ***proximal portion*** of the pull wire 12 to the tubular member 10. To the contrary, the Brennen pull wire 12 is secured to the pivotable lever 34.

As the Whayne and Brennen patents fail to teach or suggest the respective combinations of elements recited in claims 24-26 (which by definition include the combination of elements recited in independent claim 22), applicant respectfully submits that the rejection of claims 24-26 under 35 U.S.C. § 103 is improper and must be withdrawn.

IV. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such

fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

Respectfully submitted,

7/30/02
Date

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